

I claim:

1. A method of treating a skin condition or disease characterized by  
5 ulceration, inflammation, or blistering of the skin comprising applying to the skin an allantoin-  
containing composition in a therapeutically effective amount, the allantoin-containing  
composition comprising an oil-in-water emulsion comprising:
  - (a) allantoin;
  - (b) an emulsifier system including:
    - 10 (i) beeswax; and
    - (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in  
water, the pH of the composition being from about 3.0 to about 6.0 after the addition of acid to  
bring the pH into the range of from about 3.0 to about 6.0.
- 15 2. The method of claim 1 wherein the pH of the composition is from about  
4.5 to about 5.8.
3. The method of claim 1 wherein the emulsifier is selected from the group  
consisting of ammonium lauryl sulfate, sodium lauryl sulfate, sodium laureth sulfate, sodium  
20 oleyl succinate, ammonium lauryl sulfosuccinate, sodium dodecylbenzenesulfonate, ammonium  
laureth sulfate, and sodium lauryl sarcosinate.
4. The method of claim 3 wherein the emulsifier is sodium lauryl sulfate.
- 25 5. The method of claim 1 wherein the skin condition or disease is selected  
from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic  
ulcers, and milia.
6. The method of claim 5 where the skin condition or disease is  
30 epidermolysis bullosa.

7. The method of claim 1 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

8. The method of claim 7 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

9. The method of claim 1 wherein the composition further comprises at least one of:

(a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

(c) at least one herbal extract selected from the group consisting of St. John's wort extract, witch hazel extract, chamomile extract, and arnica extract;

(d) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben;

(e) tetrasodium EDTA; and

(f) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin.

10. The method of claim 2 wherein the composition comprises:  
an oil-in-water emulsion comprising:

(a) water;

(b) sodium lauryl sulfate;

(c) propylene glycol;

(d) tetrasodium EDTA;

(e) citric acid;

(f) lanolin oil;

(g) cetyl alcohol;

(h) stearyl alcohol;

(i) beeswax;

- (j) cod liver oil;
- (k) butylated hydroxytoluene;
- (l) St. John's wort extract;
- (m) witch hazel extract;
- 5 (n) chamomile extract;
- (o) arnica extract;
- (p) methylparaben;
- (q) propylparaben;
- (r) allantoin; and
- 10 (s) fragrance.

11. The method of claim 10 wherein the composition comprises:

- (a) from about 50% to about 90% of water;
- (b) from about 0.5% to about 2.5% of 30% sodium lauryl sulfate;
- 15 (c) from about 2.0% to about 9.0% of propylene glycol;
- (d) from about 0.05% to about 0.5% of tetrasodium EDTA;
- (e) from about 0.05% to about 0.5% of citric acid;
- (f) from about 5% to about 15% of lanolin oil;
- (g) from about 3% to about 10% of cetyl alcohol;
- 20 (h) from about 1% to about 5% of stearyl alcohol;
- (i) from about 0.5% to about 2.5% of beeswax;
- (j) from about 1.0% to about 7.0% of cod liver oil;
- (k) from about 0.1% to about 1.0% of butylated hydroxytoluene;
- (l) from about 0.05% to about 0.5% of St. John's wort extract;
- 25 (m) from about 0.05% to about 0.5% of witch hazel extract;
- (n) from about 0.05% to about 0.5% of chamomile extract;
- (o) from about 0.05% to about 0.5% of arnica extract;
- (p) from about 0.1% to about 0.5% of methylparaben;
- (q) from about 0.1% to about 0.5% of propylparaben;
- 30 (r) from about 0.5% to about 2% of allantoin; and
- (s) from about 0.05% to about 0.5% of fragrance.

12. The method of claim 11 wherein the composition comprises:

- (a) from about 55% to about 75% of water;
- (b) from about 1.0% to about 2.5% of 30% sodium lauryl sulfate;
- (c) from about 3.0% to about 6.0% of propylene glycol;
- (d) from about 0.1% to about 0.3% of tetrasodium EDTA;
- (e) from about 0.08 to about 0.35% of citric acid;
- (f) from about 8.0% to about 12.0% of lanolin oil;
- (g) from about 3.5% to about 7.5% of cetyl alcohol;
- (h) from about 1.0% to about 3.0% of stearyl alcohol;
- (i) from about 1.0% to about 2.5% of beeswax;
- (j) from about 1.0% to about 4.0% of cod liver oil;
- (k) from about 0.2% to about 0.8% of butylated hydroxytoluene;
- (l) from about 0.05% to about 0.15% of St. John's wort extract;
- (m) from about 0.05% to about 0.15% of witch hazel extract;
- (n) from about 0.05% to about 0.15% of chamomile extract;
- (o) from about 0.05% to about 0.15% of arnica extract;
- (p) from about 0.15% to about 0.40% of methylparaben;
- (q) from about 0.10% to about 0.30% of propylparaben;
- (r) from about 0.50% to about 2.0% of allantoin; and
- (s) from about 0.1% to about 0.3% of fragrance.

13. The method of claim 12 wherein the composition comprises:

- (a) about 68.68% of water;
- (b) about 1.9% of sodium lauryl sulfate;
- (c) about 5.3% of propylene glycol;
- (d) about 0.15% of tetrasodium EDTA;
- (e) about 0.12% of citric acid;
- (f) about 10.6% of lanolin oil;
- (g) about 4.2% of cetyl alcohol;
- (h) about 2.0% of stearyl alcohol;

- (i) about 1.90% of beeswax;
- (j) about 2.0% of cod liver oil;
- (k) about 0.5% of butylated hydroxytoluene;
- (l) about 0.1% of St. John's wort extract;
- (m) about 0.1% of witch hazel extract;
- (n) about 0.1% of chamomile extract;
- (o) about 0.1% of arnica extract;
- (p) about 0.3% of methylparaben;
- (q) about 0.25% of propylparaben;
- (r) about 1.50% of allantoin; and
- (s) about 0.20% of fragrance.

14. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

- (a) allantoin;
- (b) an emollient component comprising:
  - (i) lanolin oil;
  - (ii) cetyl alcohol;
  - (iii) stearyl alcohol; and
  - (iv) cod liver oil; and

(c) butylated hydroxytoluene;

(d) an emulsifier system comprising at least one nonionic emulsifier that is an ethoxylated ether or an ethoxylated ester whose carbon chain length ranges from 8 to 22 carbon atoms; and

(e) at least one acid selected from the group consisting of:

(i) an organic acid of from 2 to 22 carbon atoms; and

(ii) an inorganic acid selected from the group consisting of hydrochloric

acid, sulfuric acid, and phosphoric acid to adjust the pH from about 3.0 to about 6.0.

15. The method of claim 14 wherein the pH of the composition is from about 4.5 to about 5.8.

16. The method of claim 14 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

17. The method of claim 16 wherein the skin condition or disease is epidermolysis bullosa.

18. The method of claim 14 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

19. The method of claim 18 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

20. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

(a) allantoin;

(b) an emulsifier system including at least one nonionic emulsifier that is an ethoxylated ether or an ethoxylated ester whose carbon chain length ranges from 8 to 22 carbon atoms, the pH of the emulsion being from about 3.0 to about 6.0 after the addition of acid to bring the pH into the range of from about 3.0 to about 6.0.

21. The method of claim 20 wherein the pH of the composition is from about 4.5 to about 5.8.

22. The method of claim 20 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

5 23. The method of claim 22 wherein the skin condition or disease is epidermolysis bullosa.

24. The method of claim 20 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

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25. The method of claim 24 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

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26. The method of claim 20 wherein the composition further comprises at least one of:

(a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

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(c) at least one herbal extract selected from the group consisting of St. John's wort extract, witch hazel extract, chamomile extract, and arnica extract;

(d) a preservative component comprising at least one preservative selected from the group consisting methylparaben, propylparaben, and diazolidinyl urea;

(e) tetrasodium EDTA; and

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(f) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin.

27. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

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- (a) allantoin; and
- (b) an emulsifier system comprising:
  - (1) an acidic anionic polymer; and
  - (2) a polyethylene glycol ester of stearic acid;

5 wherein the pH of the composition is adjusted to a value within a range of from about 3.0 to about 6.0.

28. The method of claim 27 wherein the pH of the composition is from about 5.0 to about 6.0.

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29. The method of claim 27 wherein the acidic anionic polymer is a carboxypolymethylene polymer.

30. The method of claim 27 wherein the composition further comprises a  
15 carbohydrate polymer selected from the group consisting of galactoarabinan, polygalactose, and polyarabinose.

31. The method of claim 30 wherein the carbohydrate polymer is galactoarabinan.

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32. The method of claim 27 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

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33. The method of claim 32 wherein the skin condition or disease is epidermolysis bullosa.

34. The method of claim 27 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

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35. The method of claim 34 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

- 5                    36. The method of claim 27 wherein the composition further comprises:
- (a) an emollient component comprising at least one emollient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;
  - (b) butylated hydroxytoluene;
  - (c) a solvent component comprising at least one solvent selected from the
  - 10 group consisting of propylene glycol, glycerin, and ethylene glycol; and
  - (d) a preservative component comprising at least one preservative selected from the group consisting of methylparaben, propylparaben, and diazolidinyl urea.

- 15                    37. The method of claim 28 wherein the composition comprises:
- (a) from about 50.0% to about 90.0% of water;
  - (b) from about 0.30% to about 3.0% of a carboxypolymethylene polymer;
  - (c) from about 2.0% to about 9.0% of propylene glycol;
  - (d) from about 0.25% to about 2.5% of PEG-100 stearate;
  - (e) from about 5.0% to about 15.0% of lanolin oil;
  - 20 (f) from about 1.0% to about 8.0% of cetyl alcohol;
  - (g) from about 0.5% to about 6.0% of stearyl alcohol;
  - (h) from about 1.0% to about 7.0% of cod liver oil;
  - (i) from about 0.10% to about 1.0% of butylated hydroxytoluene;
  - (j) from about 0.10% to about 0.50% of methylparaben;
  - 25 (k) from about 0.10% to about 0.50% of propylparaben;
  - (l) from about 0.05% to about 0.25% of diazolidinyl urea;
  - (m) from about 0.50% to about 2.0% of allantoin;
  - (n) from about 0.05% to about 0.50% of fragrance; and
  - (o) from about 0.05% to about 3.0% of triethanolamine.

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38. The method of claim 37 wherein the composition comprises:

- 5 (a) from about 60.0% to about 85.0% of water;  
(b) from about 0.50% to about 2.0% of a carboxypolymethylene polymer;  
(c) from about 4.0% to about 7.0% of propylene glycol;  
(d) from about 0.50% to about 2.0% of PEG-100 stearate;  
(e) from about 8.0% to about 12.0% of lanolin oil;  
(f) from about 2.0% to about 7.0% of cetyl alcohol;  
(g) from about 0.75% to about 5.0% of stearyl alcohol;  
(h) from about 1.0% to about 4.0% of cod liver oil;  
10 (i) from about 0.20% to about 0.80% of butylated hydroxytoluene;  
(j) from about 0.15% to about 0.40% of methylparaben;  
(k) from about 0.15% to about 0.45% of propylparaben;  
(l) from about 0.10% to about 0.20% of diazolidinyl urea;  
(m) from about 1.0% to about 2.0% of allantoin;  
(n) from about 0.10% to about 0.40% of fragrance; and  
15 (o) from about 0.20% to about 2.0% of triethanolamine.

39. The method of claim 38 wherein the composition comprises:  
(a) about 69.95% of water;  
(b) about 0.85% of a carboxypolymethylene polymer;  
20 (c) about 5.70% of propylene glycol;  
(d) about 2.0% of PEG-100 stearate;  
(e) about 10.60% of lanolin oil;  
(f) about 4.20% of cetyl alcohol;  
(g) about 1.50% of stearyl alcohol;  
25 (h) about 2.00% of cod liver oil;  
(i) about 0.50% of butylated hydroxytoluene;  
(j) about 0.30% of methylparaben;  
(k) about 0.25% of propylparaben;  
(l) about 0.15% of diazolidinyl urea;  
30 (m) about 1.50% of allantoin;  
(n) about 0.20% of fragrance; and

- (o) about 0.80% of triethanolamine.

40. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-  
5 containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

(a) allantoin; and

(b) an emulsifier system comprising:

(i) an acidic anionic polymer; and

10 (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water, the pH of the composition being adjusted to a range from about 3.0 to about 6.0.

41. The method of claim 40 wherein the pH of the composition is from about 5.0 to about 6.0.

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42. The method of claim 40 wherein the anionic emulsifier is selected from the group consisting of sodium lauryl sulfate, sodium laureth sulfate, sodium oleyl succinate, sodium dodecylbenzenesulfonate and sodium lauryl sarcosinate.

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43. The method of claim 42 wherein the anionic emulsifier is sodium lauryl sulfate.

44. The method of claim 40 wherein the acidic anionic polymer is carboxypolymethylene.

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45. The method of claim 44 wherein the composition further comprises a carbohydrate polymer selected from the group consisting of galactoarabinan, polygalactose and polyarabinose.

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46. The method of claim 45 wherein the carbohydrate polymer is galactoarabinan.

47. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

(a) allantoin; and

(b) an emulsifier system comprising:

(i) an acidic anionic polymer; and

(ii) a nonionic emulsifier that is an ethoxylated ether or an ethoxylated ester whose carbon chain length ranges from 8 to 22 carbon atoms, wherein the pH of the composition is from about 3.0 to about 6.0.

48. The method of claim 47 wherein the pH of the composition is from about 5.0 to about 6.0.

49. The method of claim 47 wherein the acidic anionic polymer is carboxypolymethylene.

50. The method of claim 47 wherein the composition further comprises a carbohydrate polymer selected from the group consisting of galactoarabinan, polygalactose and polyarabinose.

51. The method of claim 50 wherein the carbohydrate polymer is galactoarabinan.

52. The method of claim 47 wherein the emulsifier system further comprises glyceryl stearate.

53. The method of claim 47 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

54. The method of claim 53 wherein the skin condition or disease is epidermolysis bullosa.

5 55. The method of claim 47 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

56. The method of claim 55 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene  
10 antagonists, and monoclonal antibodies.

57. The method of claim 47 wherein the composition further comprises at least one of:

(a) an emollient component comprising at least one emollient selected from the  
15 group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

(c) at least one herbal extract selected from the group consisting of St. John's wort extract, witch hazel extract, chamomile extract, and arnica extract;

(d) a preservative component comprising at least one preservative selected from  
20 the group consisting of methylparaben, propylparaben and diazolidinyl urea;

(e) tetrasodium EDTA; and

(f) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin.

25 58. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

(a) allantoin;

30 (b) an emulsifier system comprising an acidic anionic polymer;

(c) an organic or inorganic base to adjust the pH to a value in a range of from about 3.0 to about 6.0

5 59. The method of claim 58 wherein the pH of the composition is from about 5.0 to about 5.5.

60. The method of claim 58 wherein the organic or inorganic base is triethanolamine.

10 61. The method of claim 58 wherein the acidic anionic polymer is carboxypolymethylene.

62. The method of claim 58 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic  
15 ulcers, and milia.

63. The method of claim 62 wherein the skin condition or disease is epidermolysis bullosa.

20 64. The method of claim 58 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

65. The method of claim 64 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene  
25 antagonists, and monoclonal antibodies.

66. The method of claim 58 wherein the composition further comprises at least one of:

30 (a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

(c) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben; and

(d) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin.

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67. The method of claim 59 wherein the composition comprises:

- (a) from about 50.0% to about 90.0% of water;
- (b) from about 0.40% to about 3.0% of carboxypolymethylene polymer;
- (c) from about 2.0% to about 9.0% of propylene glycol.
- (d) from about 5.0% to about 15.0% of lanolin oil;
- (e) from about 1.0% to about 8.0% of cetyl alcohol;
- (f) from about 1.0% to about 7.0% of cod liver oil;
- (g) from about 0.10% to about 1.0% of butylated hydroxytoluene;
- (h) from about 0.10% to about 0.50% of methylparaben;
- (i) from about 0.10% to about 0.50% of propylparaben;
- (j) from about 0.50% to about 2.0% of allantoin;
- (k) from about 0.05% to about 0.5% of fragrance; and
- (l) from about 0.05% to about 3.0% of 95% triethanolamine.

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68. The method of claim 67 wherein the composition comprises:

- (a) from about 60.0% to about 80.0% of water;
- (b) from about 0.50% to about 2.0% of carboxypolymethylene polymer;
- (c) from about 4.0% to about 7.0% of propylene glycol.
- (d) from about 8.0% to about 12.0% of lanolin oil;
- (e) from about 2.0% to about 7.0% of cetyl alcohol;
- (f) from about 1.0% to about 4.0% of cod liver oil;
- (g) from about 0.30% to about 0.80% of butylated hydroxytoluene;
- (h) from about 0.15% to about 0.40% of methylparaben;
- (i) from about 0.15% to about 0.40% of propylparaben;
- (j) from about 1.0% to about 2.0% of allantoin;
- (k) from about 0.10% to about 0.40% of fragrance; and

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(l) from about 0.20% to about 2.0% of 95% triethanolamine.

69. The method of claim 68 wherein the composition comprises:

- (a) about 73.55% of water;
- (b) about 1.00% of carboxypolymethylene polymer;
- (c) about 5.7% of propylene glycol.
- (d) about 10.0% of lanolin oil;
- (e) about 3.00% of cetyl alcohol;
- (f) about 2.00% of cod liver oil;
- (g) about 0.50% of butylated hydroxytoluene;
- (h) about 0.30% of methylparaben;
- (i) about 0.25% of propylparaben;
- (j) about 1.50% of allantoin;
- (k) about 0.20% of fragrance; and
- (l) about 0.80% of 95% triethanolamine.

70. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

- (a) allantoin;
- (b) an emulsifier system comprising:
  - (i) cetyl alcohol; and
  - (ii) stearic acid; and
- (c) a weak organic base to adjust the pH to a range of from about 3.0 to about 6.0.

71. The method of claim 70 wherein the pH of the composition is from about 5.0 to about 5.8.

72. The method of claim 70 wherein the weak organic base is triethanolamine.



73. The method of claim 70 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

5 74. The method of claim 73 wherein the skin condition or disease is epidermolysis bullosa.

75. The method of claim 70 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

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76. The method of claim 75 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

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77. The method of claim 70 wherein the composition further comprises at least one of:

(a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, stearyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

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(c) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben; and

(d) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin.

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78. The method of claim 71 wherein the composition comprises:

(a) from about 50.0% to about 90.0% of water;

(b) from about 2.0% to about 9.0% of propylene glycol;

(c) from about 0.2% to about 4.0% of triethanolamine;

(d) from about 5.0% to about 15.0% of lanolin oil;

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(e) from about 1.0% to about 7.0% of cetyl alcohol;

(f) from about 0.50% to about 5.0% of stearic acid;

- (g) from about 1.0% to about 7.0% of cod liver oil;  
(h) from about 0.10% to about 1.0% of butylated hydroxytoluene;  
(i) from about 0.10% to about 0.50% of methylparaben;  
(j) from about 0.10% to about 0.50% of propylparaben;  
(k) from about 0.50% to about 2.0% of allantoin; and  
(l) from about 0.05% to about 0.50% of fragrance.

79. The method of claim 78 wherein the composition comprises:

- (a) from about 60.0% to about 85.0% of water;  
(b) from about 4.0% to about 7.0% of propylene glycol;  
(c) from about 0.5% to about 3.0% of triethanolamine;  
(d) from about 8.0% to about 12.0% of lanolin oil;  
(e) from about 2.0% to about 6.0% of cetyl alcohol;  
(f) from about 1.0% to about 4.0% of stearic acid;  
(g) from about 1.5% to about 5.0% of cod liver oil;  
(h) from about 0.20% to about 0.80% of butylated hydroxytoluene;  
(i) from about 0.15% to about 0.40% of methylparaben;  
(j) from about 0.15% to about 0.40% of propylparaben;  
(k) from about 1.0% to about 2.0% of allantoin; and  
(l) from about 0.10% to about 0.40% of fragrance.

80. The method of claim 79 wherein the composition comprises:

- (a) about 71.70% of water;  
(b) about 5.70% of propylene glycol;  
(c) about 1.25% of triethanolamine;  
(d) about 10.60% of lanolin oil;  
(e) about 3.50% of cetyl alcohol;  
(f) about 2.50% of stearic acid;  
(g) about 2.00% of cod liver oil;  
(h) about 0.50% of butylated hydroxytoluene;  
(i) about 0.30% of methylparaben;

- (j) about 0.25% of propylparaben;
- (k) about 1.50% of allantoin; and
- (l) about 0.20% of fragrance.

5           81. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

- (a) allantoin;
- 10       (b) an emulsifier system comprising:
  - (i) sodium stearoyl lactylate;
  - (ii) sodium isostearoyl lactylate;
  - (iii) optionally, triethanolamine stearate;
  - (iv) optionally, at least one nonionic emulsifier selected from the group
- 15       consisting of a nonionic emulsifier that is an ethoxylated ether or an ethoxylated ester whose carbon chain length ranges from 8 to 22 carbon atoms; and
- (c) an acid to adjust the pH to a range of from about 3.0 to about 6.0.

20           82. The method of claim 81 wherein the pH of the composition is from about 5.0 to about 5.8.

83. The method of claim 81 wherein the acid is citric acid.

25           84. The method of claim 81 wherein the composition comprises triethanolamine stearate.

30           85. The method of claim 81 wherein the composition comprises at least one nonionic emulsifier selected from the group consisting of a nonionic emulsifier that is an ethoxylated ether or an ethoxylated ester whose carbon chain length ranges from 8 to 22 carbon atoms.

86. The method of claim 81 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

5 87. The method of claim 86 wherein the skin condition or disease is epidermolysis bullosa.

88. The method of claim 81 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

10 89. The method of claim 88 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

15 90. The method of claim 81 wherein the composition further comprises at least one of:

(a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, cetyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

20 (c) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben;

(d) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin; and

(e) tetrasodium EDTA.

25 91. The method of claim 82 wherein the composition comprises:

(a) from about 50.0% to about 90.0% of water;

(b) from about 2.0% to about 9.0% of propylene glycol;

(c) from about 0.05% to about 0.5% of citric acid;

30 (d) from about 0.30% to about 3.0% of sodium stearoyl lactylate;

(e) from about 0.05% to about 1.0% of sodium isostearoyl lactylate;

- (f) from about 0.05% to about 0.25% of tetrasodium EDTA;  
(g) from about 5.0% to about 15.0% of lanolin oil;  
(h) from about 1.0% to about 8.0% of cetyl alcohol;  
(i) from about 1.0% to about 7.0% of cod liver oil;  
(j) from about 0.10% to about 1.0% of butylated hydroxytoluene;  
(k) from about 0.10% to about 0.50% of methylparaben;  
(l) from about 0.10% to about 0.50% of propylparaben;  
(m) from about 0.50% to about 2.0% of allantoin; and  
(n) from about 0.05% to about 0.50% of fragrance.

92. The method of claim 91 wherein the composition comprises:

- (a) from about 60.0% to about 80.0% of water;  
(b) from about 4.0% to about 7.0% of propylene glycol;  
(c) from about 0.10% to about 0.40% of citric acid;  
(d) from about 0.50% to about 2.5% of sodium stearoyl lactylate;  
(e) from about 0.10% to about 0.70% of sodium isostearoyl lactylate;  
(f) from about 0.10% to about 0.20% of tetrasodium EDTA;  
(g) from about 8.0% to about 12.0% of lanolin oil;  
(h) from about 2.0% to about 7.0% of cetyl alcohol;  
(i) from about 1.0% to about 4.0% of cod liver oil;  
(j) from about 0.20% to about 0.80% of butylated hydroxytoluene;  
(k) from about 0.15% to about 0.40% of methylparaben;  
(l) from about 0.15% to about 0.40% of propylparaben;  
(m) from about 1.0% to about 2.0% of allantoin; and  
(n) from about 0.10% to about 0.40% of fragrance.

93. The method of claim 92 wherein the composition comprises:

- (a) about 73.42% of water;  
(b) about 5.70% of propylene glycol;  
(c) about 0.18% of citric acid;  
(d) about 1.00% of sodium stearoyl lactylate;

- (e) about 0.25% of sodium isostearoyl lactylate;
- (f) about 0.15% of tetrasodium EDTA;
- (g) about 15.0% of lanolin oil;
- (h) about 3.80% of cetyl alcohol;
- (i) about 2.00% of cod liver oil;
- (j) about 0.50% of butylated hydroxytoluene;
- (k) about 0.30% of methylparaben;
- (l) about 0.25% of propylparaben;
- (m) about 1.50% of allantoin; and
- (n) about 0.20% of fragrance.

94. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

- (a) allantoin; and
- (b) an emulsifier system comprising at least one polyethyleneglycol ether of cetearyl alcohol, wherein the number of polyethylene glycol moieties in the polyethyleneglycol ether of cetearyl alcohol is from 6 to 40; and
- (c) an acid to adjust the pH of the composition to a range of from about 3.0 to about 6.0.

95. The method of claim 94 wherein the pH of the composition is from about 5.0 to about 5.8.

96. The method of claim 94 wherein the acid is citric acid.

97. The method of claim 94 wherein the emulsifier system comprises cetareth-25 and cetareth-6.

98. The method of claim 94 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

5 99. The method of claim 98 wherein the skin condition or disease is epidermolysis bullosa.

100. The method of claim 94 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

10 101. The method of claim 100 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

15 102. The method of claim 94 wherein the composition further comprises at least one of:

(a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

20 (c) a preservative component comprising at least one preservative selected from the group consisting of methylparaben, propylparaben, and diazolidinyi urea;

(d) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin; and

(e) tetrasodium EDTA.

25 103. The method of claim 95 wherein the composition comprises:

(a) from about 50.0% to about 90.0% of water;

(b) from about 2.0% to about 9.0% of propylene glycol;

(c) from about 0.05% to about 0.50% of tetrasodium EDTA;

30 (d) from about 0.50% to about 4.0% of cetareth-25;

(e) from about 0.04% to about 0.40% of citric acid;

- (f) from about 5.0% to about 15.0% of lanolin oil;  
(g) from about 3.0% to about 10.0% of cetyl alcohol;  
(h) from about 1.0% to about 5.0% of stearyl alcohol;  
(i) from about 0.50% to about 4.0% of ceteareth-6;  
(j) from about 1.0% to about 7.0% of cod liver oil;  
(k) from about 0.1% to about 1.0% of butylated hydroxytoluene;  
(l) from about 0.10% to about 0.50% of methylparaben;  
(m) from about 0.10% to about 0.50% of propylparaben;  
(n) from about 0.05% to about 0.50% of diazolidinyl urea;  
(o) from about 0.50% to about 2.0% of allantoin; and  
(p) from about 0.05% to about 0.50% of fragrance.

104. The method of claim 103 wherein the composition comprises:

- (a) from about 55.0% to about 75.0% of water;  
(b) from about 4.2% to about 7.0% of propylene glycol;  
(c) from about 0.10% to about 0.30% of tetrasodium EDTA;  
(d) from about 2.0% to about 3.5% of ceteareth-25;  
(e) from about 0.10% to about 0.30% of citric acid;  
(f) from about 8.0% to about 12.0% of lanolin oil;  
(g) from about 3.5% to about 7.5% of cetyl alcohol;  
(h) from about 2.0% to about 4.0% of stearyl alcohol;  
(i) from about 1.0% to about 3.0% of ceteareth-6;  
(j) from about 1.0% to about 4.0% of cod liver oil;  
(k) from about 0.20% to about 0.80% of butylated hydroxytoluene;  
(l) from about 0.15% to about 0.40% of methylparaben;  
(m) from about 0.15% to about 0.40% of propylparaben;  
(n) from about 0.10% to about 0.30% of diazolidinyl urea;  
(o) from about 1.0% to about 2.0% of allantoin; and  
(p) from about 0.10% to about 0.30% of fragrance.

105. The method of claim 104 wherein the composition comprises:



- 5 (a) about 66.33% of water;  
(b) about 5.70% of propylene glycol;  
(c) about 0.15% of tetrasodium EDTA;  
(d) about 2.60% of cetareth-25;  
(e) about 0.12% of citric acid;  
(f) about 10.60% of lanolin oil;  
(g) about 4.30% of cetyl alcohol;  
(h) about 3.50% of stearyl alcohol;  
(i) about 1.80% of cetareth-6;  
10 (j) about 2.00% of cod liver oil;  
(k) about 0.50% of butylated hydroxytoluene;  
(l) about 0.30% of methylparaben;  
(m) about 0.25% of propylparaben;  
(n) about 0.15% of diazolidinyl urea;  
15 (o) about 1.50% of allantoin; and  
(p) about 0.20% of fragrance.

106. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-  
20 containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

- (a) allantoin;  
(b) an emulsifier system comprising:  
25 (i) a polyethylene glycol ester of stearic acid; and  
(ii) glyceryl stearate; and  
(c) an acid to adjust the pH of the composition to a range of from about 3.0 to  
about 6.0.

107. The method of claim 106 wherein the pH of the composition is from about  
30 5.0 to about 5.8.

108. The method of claim 106 wherein the number of ethylene glycol moieties in the polyethylene glycol ester of stearic acid is from 25 to 100.

109. The method of claim 106 wherein the polyethylene glycol ester of stearic acid is PEG-100 stearate.

110. The method of claim 106 wherein the acid is citric acid.

111. The method of claim 106 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

112. The method of claim 111 wherein the skin condition or disease is epidermolysis bullosa.

113. The method of claim 106 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

114. The method of claim 113 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

115. The method of claim 107 wherein the composition further comprises at least one of:

(a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;

(b) butylated hydroxytoluene;

(c) a preservative component comprising at least one preservative selected from the group consisting of methylparaben, propylparaben, and diazolidinyl urea;

(d) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin; and

(e) tetrasodium EDTA.

116. The method of claim 108 wherein the composition comprises:

- (a) from about 50.0% to about 90.0% of water;
- (b) from about 2.0% to about 9.0% of propylene glycol;
- (c) from about 0.05% to about 0.50% of tetrasodium EDTA;
- (d) from about 0.04% to about 0.40% of citric acid;
- (e) from about 1.0% to about 5.0% of PEG-100 stearate;
- (f) from about 5.0% to about 15.0% of lanolin oil;
- (g) from about 2.0% to about 10.0% of cetyl alcohol;
- (h) from about 1.0% to about 4.0% of stearyl alcohol;
- (i) from about 1.0% to about 5.0% of glyceryl stearate;
- (j) from about 1.0% to about 7.0% of cod liver oil;
- (k) from about 0.10% to about 1.0% of butylated hydroxytoluene;
- (l) from about 0.10% to about 0.50% of methylparaben;
- (m) from about 0.10% to about 0.50% of propylparaben;
- (n) from about 0.05% to about 0.50% of diazolidinyl urea;
- (o) from about 0.50% to about 2.0% of allantoin; and
- (p) from about 0.05% to about 0.50% of fragrance.

117. The method of claim 116 wherein the composition comprises:

- (a) from about 55.0% to about 80.0% of water;
- (b) from about 4.0% to about 7.0% of propylene glycol;
- (c) from about 0.10% to about 0.30% of tetrasodium EDTA;
- (d) from about 0.10% to about 0.30% of citric acid;
- (e) from about 1.50% to about 3.0% of PEG-100 stearate;
- (f) from about 8.0% to about 12.0% of lanolin oil;
- (g) from about 2.5% to about 7.5% of cetyl alcohol;
- (h) from about 1.0% to about 3.5% of stearyl alcohol;
- (i) from about 2.0% to about 4.0% of glyceryl stearate;
- (j) from about 1.0% to about 4.0% of cod liver oil;

- (k) from about 0.20% to about 0.80% of butylated hydroxytoluene;  
(l) from about 0.15% to about 0.40% of methylparaben;  
(m) from about 0.15% to about 0.40% of propylparaben;  
(n) from about 0.10% to about 0.30% of diazolidinyl urea;  
(o) from about 1.0% to about 2.0% of allantoin; and  
(p) from about 0.10% to about 0.40% of fragrance.

118. The method of claim 117 wherein the composition comprises:

- (a) about 67.86% of water;  
(b) about 5.70% of propylene glycol;  
(c) about 0.15% of tetrasodium EDTA;  
(d) about 0.14% of citric acid;  
(e) about 2.60% of PEG-100 stearate;  
(f) about 10.60% of lanolin oil;  
(g) about 3.00% of cetyl alcohol;  
(h) about 2.50% of stearyl alcohol;  
(i) about 2.50% of glyceryl stearate;  
(j) about 2.00% of cod liver oil;  
(k) about 0.50% of butylated hydroxytoluene;  
(l) about 0.30% of methylparaben;  
(m) about 0.25% propylparaben;  
(n) about 0.20% of diazolidinyl urea;  
(o) about 1.50% to about 2.0% of allantoin; and  
(p) about 0.20% of fragrance.

119. A method of treating a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin, comprising applying to the skin an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

- (a) allantoin;  
(b) a carbohydrate polymer; and

(c) an emulsifier system comprising:

(1) beeswax; and

(2) an anionic emulsifier that is substantially hydrophilic and is soluble in water;

5 wherein the pH of the composition is between about 3.0 and about 6.0.

120. The method of claim 119 wherein the pH of the composition is between about 5.0 and about 6.0.

10 121. The method of claim 119 wherein the carbohydrate polymer is selected from the group consisting of galactoarabinan, polygalactose, and polyarabinose.

122. The method of claim 119 wherein the carbohydrate polymer is galactoarabinan.

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123. The method of claim 119 wherein the anionic emulsifier that is substantially hydrophilic and soluble in water is selected from the group consisting of sodium lauryl sulfate, sodium laureth sulfate, sodium oleyl succinate, sodium dodecylbenzenesulfonate, and sodium lauryl sarcosinate.

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124. The method of claim 123 wherein the anionic emulsifier that is substantially hydrophilic and soluble in water is sodium lauryl sulfate.

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125. The method of claim 119 wherein the composition further comprises citric acid.

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126. The method of claim 119 wherein the skin condition or disease is selected from the group consisting of epidermolysis bullosa, decubitus ulcers, pressure ulcers, diabetic ulcers, and milia.

127. The method of claim 126 wherein the skin condition or disease is epidermolysis bullosa.

128. The method of claim 119 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

129. The method of claim 128 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

130. The method of claim 119 wherein the composition further comprises at least one of:

(a) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin;

(b) an emollient component comprising at least one emollient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil;

(c) butylated hydroxytoluene;

(d) tetrasodium EDTA; and

(e) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben.

131. The method of claim 120 wherein the composition comprises:

(a) from about 50.0% to about 90.0% of water;

(b) from about 2.0% to about 9.0% of propylene glycol;

(c) from about 0.50% to about 5.0% of a 30% solution of sodium lauryl sulfate;

(d) from about 0.05% to about 0.30% of tetrasodium EDTA;

(e) from about 1.0% to about 25.0% of galactoarabinan;

(f) from about 0.05% to about 0.25% of citric acid;

(g) from about 5.0% to about 15.0% of lanolin oil;

(h) from about 1.0% to about 8.0% of cetyl alcohol;

- 5 (i) from about 0.50% to about 6.0% of stearyl alcohol;  
 (j) from about 0.50% to about 5.0% of beeswax;  
 (k) from about 0.50% to about 15.0% of cod liver oil;  
 (l) from about 0.1% to about 3.0% of butylated hydroxytoluene;  
 (m) from about 0.10% to about 0.50% of methylparaben;  
 (n) from about 0.10% to about 0.50% of propylparaben;  
 (o) from about 0.50% to about 2.0% of allantoin; and  
 (p) from about 0.05% to about 0.50% of fragrance.
- 10 132. The method of claim 131 wherein the composition comprises:  
 (a) from about 60.0% to about 80.0% of water;  
 (b) from about 4.0% to about 7.0% of propylene glycol;  
 (c) from about 1.0% to about 3.0% of a 30% solution of sodium lauryl sulfate;  
 (d) from about 0.10% to about 0.20% of tetrasodium EDTA;  
 15 (e) from about 3.0% to about 15.0% of galactoarabinan;  
 (f) from about 0.10% to about 0.20% of citric acid;  
 (g) from about 8.0% to about 12.0% of lanolin oil;  
 (h) from about 2.0% to about 7.0% of cetyl alcohol;  
 (i) from about 1.0% to about 4.0% of stearyl alcohol;  
 20 (j) from about 1.0% to about 3.0% of beeswax;  
 (k) from about 1.0% to about 10.0% of cod liver oil;  
 (l) from about 0.25% to about 2.50% of butylated hydroxytoluene;  
 (m) from about 0.15% to about 0.40% of methylparaben;  
 (n) from about 0.15% to about 0.40% of propylparaben;  
 25 (o) from about 1.0% to about 2.0% of allantoin; and  
 (p) from about 0.10% to about 0.40% of fragrance.
- 30 133. The method of claim 132 wherein the composition comprises:  
 (a) about 61.65% of water;  
 (b) about 5.70% of propylene glycol;  
 (c) about 1.90% of a 30% solution of sodium lauryl sulfate;

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- (d) about 0.15% of tetrasodium EDTA;
- (e) about 5.00% of galactoarabinan;
- (f) about 0.15% of citric acid;
- (g) about 10.60% of lanolin oil;
- (h) about 4.20% of cetyl alcohol;
- (i) about 2.00% of stearyl alcohol;
- (j) about 1.90% of beeswax;
- (k) about 2.00% of cod liver oil;
- (l) about 0.50% of butylated hydroxytoluene;
- (m) about 0.30% of methylparaben;
- (n) about 0.25% of propylparaben;
- (o) about 1.50% of allantoin; and
- (p) about 0.20% of fragrance.

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